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EXAMINER	
LOUIS, LATOYA M	

ART UNIT	PAPER NUMBER
3771	

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12/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,034	BASSIN, DAVID	
	Examiner	Art Unit	
	LaToya Louis	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *112-134* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *112-134* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is responsive to the claims filed 12/9/2010. As directed, no claims have been added, cancelled, or amended. Thus claims 112-134 are currently pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 113-120 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 113, the limitation "the amplitude" lacks antecedent basis.

Regarding claim 117, the limitations "the current breathing cycle" and "the amplitude" lack antecedent basis.

Claims 114-116 and 118-120 are rejected for their dependency on a rejected claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 112-115, 121, 122, 125, and 128-134 are rejected under 35 U.S.C. 102(b) as being anticipated by Berthon-Jones (EP 1,129,742 A2).

Regarding claim 112, Berthon-Jones teaches in fig. 2 an apparatus for providing ventilatory pressure support to a patient comprising a control mechanism (i.e. 16) for deriving two calculated errors (page 6 lines 45-56 discloses a formula, 5 lfl-V_{TGT}, for calculating at least two errors values. As disclosed the first calculated error results when 5 lfl-V_{TGT} = negative indicating that the patient in under ventilated and requires more and sudden ventilatory support. A second calculated error results when 5 lfl-V_{TGT} = positive indicating the subject is over ventilated and requires less and smoother ventilatory support. In addition, multiple calculated error values will result from 5 lfl-V_{TGT} depending on the measured values of airflow. [0031] and [0042] disclose large negative error values as alternative first calculated error indicating that the patient is grossly under ventilated and requires faster ventilator support and small negative error values as alternative second calculated error indicating that the patient is mildly under ventilated and requires smoother ventilator support) each of which is a function of the same target ventilation value (V_{TGT}) and a respective one of two patient ventilation measures the two patient ventilation measures having respective relatively fast and relatively slow speeds of response to the calculated errors,(i.e. a measured airflow value that is grossly under V_{TGT} as first ventilation measure having K=0 and a measured airflow value that is over or only slightly below V_{TGT} as second ventilation measure having K=1), the control mechanism further deriving two control responses of pressure to respective ones of the two calculated errors (As indicated in [0029] and shown in figs. 3 and 4, The first control response is when $\Pi(\Phi)$ becomes a square wave causing a sudden and efficient pressure response when K=0 as a result of the a first calculated error and the second control response is when $\Pi(\Phi)$ becomes a smoother wave causing a smoother less efficient pressure response when K=1 as a result of the second calculated error) and combining

the two control responses to produce an overall control response that increasingly favors the first control response (square wave) as the first ventilation measure (airflow below or grossly below V_{TGT}) becomes increasingly less than the target ventilation value (page 7 lines 1-25 and [0038]), and a ventilator (i.e. 19) responsive to the overall control response for controlling the level of pressure of air delivered to said patient (page 4 lines 10-14).

Regarding claim 113, Berthon-Jones discloses that each of the two control responses is a function of the amplitude and sign of the respective one of the calculated errors (page 6 lines 25-26 and 45-55) so that the first control response (square wave) is more vigorous than the second control response (smooth wave) ([0022]).

Regarding claims 114, 121, 129, and 130 Berthon-Jones discloses that the degree of control and gain exercised by the ventilator servo control mechanism increases with the magnitudes of the two calculated errors (page 7 lines 10 and 25-35).

Regarding claims 115, 122, and 131 Berthon-Jones discloses that the degree of control/servo exercised by the ventilator is greater (has a greater gain G) for calculated errors below the target value (page 7 lines 25-31 and the code found on lines 40-51 indicate that for calculated errors above V_{TGT} only amplitude A decreases but for calculated errors below V_{TGT} K in incremented towards 1, making the wave more square, and the amplitude A increases thereby providing a greater degree of control).

Regarding claim 125, Berthon-Jones discloses that the control mechanism further determines the phase of the current breathing cycle ([0020]) and adjusts the overall control response to be a function of the amplitude at the determined phase of the current breathing cycle

of an amplitude-versus-phase template that is appropriate for a normal breathing cycle ([0019] and page 5 lines 21-36 disclose that the control response, being dependent on K, is a function of amplitude A at a particular breathing phase of a pressure waveform template $\Pi(\Phi)$.

Regarding claim 128, Berthon-Jones discloses that each of the calculated errors is a clipped integral of the respective patient ventilation measure minus said target value ([0032]).

Regarding claim 132, Berthon-Jones discloses that the gain is varied more aggressively for conditions of hypoventilation than for conditions of hyperventilation (page 6 lines 46-55).

Regarding claim 133, Berthon-Jones discloses that the ventilator is flow-triggered and phase cycled (page 4 lines 46-54).

Regarding claim 134, Berthon-Jones discloses that the ventilator withdraws ventilation support more gradually when the patient is over-ventilated than when the patient is under-ventilated (page 7 lines 25-31 and the code found on lines 40-51 indicate that for calculated errors above VTGT only amplitude A decreases while K remains at 0 but for calculated errors below V_{TGT} K in incremented towards 1, making the wave more square and abrupt while also increasing the amplitude).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 116, 117, 123, and 124 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berthon-Jones in view of the article entitled "An Adaptive Lung Ventilation Controller" of record by Laubscher et al.

Regarding claims 116, 123, and 124, Berthon-Jones teaches target value (V_{TGT}) but doesn't teach that the target value is an alveolar ventilation that takes into account the patient's anatomical or physiologic dead space. However, Laubscher teaches an apparatus (fig. 2) for providing ventilatory assistance wherein the target value "V'ga" is an alveolar ventilation (page 51, col. 2, 4th paragraph) that takes into account the patient's anatomical or physiologic dead space "VD" (page 52 col. 1 paragraph 2 and in formula (2) on page 51 teaches that the target value "V'ga" is a desired ventilation entered by a user as in that takes into account the patient's physiologic dead space VD). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the target value of Berthon-Jones to take into account the physiologic dead space as taught by Laubscher to provide more accurate ventilation in people with lung disease

Regarding claim 117, Berthon-Jones discloses that the control mechanism further determines the phase of the current breathing cycle ([0020]) and adjusts the overall control response to be a function of the amplitude at the determined phase of the current breathing cycle of an amplitude-versus-phase template that is appropriate for a normal breathing cycle ([0019] and page 5 lines 21-36 disclose that the control response, being dependent on K, is a function of amplitude A at a particular breathing phase of a pressure waveform template $\Pi(\Phi)$.

8. Claims 118-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berthon-Jones in view of Laubscher et al., as applied to claim 117 above, and further in view of Berthon-Jones (WO 01/19440 A1) of record hereinafter Berthon-Jones '40.

Regarding claims 118 and 119, Berthon-Jones discloses that the control mechanism determines the phase of the current breathing cycle by applying a set of fuzzy logic rules ([0020]) but does not specifically disclose that the phase is determined by relating respiratory airflow and its rate of change to different phases of a normal breathing cycle. However, Berthon-Jones '40 teaches that the phase is determined by relating respiratory airflow and its rate of change to different phases of a normal breathing cycle (Page 4 lines 4-8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the control mechanism of Berthon-Jones to determine the phase using respiratory airflow and its derivative as taught by Berthon-Jones '40 to provide an accurate and less complicated/easier to obtain means of determining the phase.

Regarding claim 119, Berthon-Jones discloses that the overall control response is a clipped integral of a function of both of the calculated errors (page 6 line 30).

9. Claims 126 and 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berthon-Jones in view of Berthon-Jones '40.

Regarding claims 126 and 127, Berthon-Jones discloses that the control mechanism determines the phase of the current breathing cycle by applying a set

of fuzzy logic rules ([0020]) but does not specifically disclose that the phase is determined by relating respiratory airflow and its rate of change to different phases of a normal breathing cycle. However, Berthon-Jones '40 teaches that the phase is determined by relating respiratory airflow and its rate of change to different phases of a normal breathing cycle (Page 4 lines 4-8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the control mechanism of Berthon-Jones to determine the phase using respiratory airflow and its derivative as taught by Berthon-Jones '40 to provide an accurate and less complicated/easier to obtain means of determining the phase.

Response to Arguments

10. Applicant's arguments filed 12/9/2010 have been fully considered but they are not persuasive.

Regarding applicant's arguments on page 9 1st paragraph, applicant argues that "the calculated error obviously has an amplitude and it should not be necessary to define it explicitly." Similarly in paragraph two, applicant argues that there is no need to explicitly define a breathing cycle. Examiner respectfully disagrees because the term "the" is a term referring back to something. Thus by using the terms "the amplitude", the sign", and "the current breathing cycle", applicant is referring back to an amplitude, sign, and breathing cycle which were never mentioned in the claim language. This renders the claims indefinite. Therefore the 112 rejections are maintained.

Regarding applicant's arguments on page 10, third full paragraph, applicant argues that in Berthon-Jones "there is only one error (0.5 lfl-V_{TGT})." Examiner respectfully disagrees. Berthon-Jones discloses a formula 0.5 lfl-V_{TGT} for calculating multiple error values (page 6 lines 45-48). The error values can have a positive sign or negative sign and [0031] and [0032] disclose that the amplitude of the error values depends on the value of the airflow and how far it is away from a target V_{TGT}. Thus multiple error values are derived from the single error formula and are used to control the ventilator.

Regarding applicant's arguments on page 11, 1st paragraph, applicant argues that in Berthon-Jones "there are not two control responses that are combined, and there certainly is no overall control response that increasingly favors one or the other of two different control responses as the claim requires." Examiner respectfully disagrees because as indicated in [0029] and shown in figs. 3 and 4, the first control response is when $\Pi(\Phi)$ becomes a square wave when K=0 causing a sudden and efficient pressure response and the second control response is when $\Pi(\Phi)$ becomes a smooth wave at K=1 causing a smoother less efficient pressure response. As disclosed on page 8 lines 1-33, K does not switch between 1 and 0 but instead is gradually increased or decreased producing intermediate values of K, i.e. K=0.4, as shown in fig. 3 which is a combined response as disclosed in [0042]. As further disclosed in [0041] and [0042] this combined response will become increasingly square favoring the first control response as the patient becomes increasingly under ventilated.

Regarding applicant's arguments on page 11 last paragraph, applicant argues that "there is only a single function that is calculated." The argument is irrelevant however, because the limitation of a single error function is not found in the claim 113 language.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya Louis whose telephone number is (571) 270-5337. The examiner can normally be reached on Monday-Friday, 8:30am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LaToya Louis/
Examiner, Art Unit 3771
12/16/2010

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772